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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,724	03/26/2007	Victor Anomah Ngu	133059-01US	2192

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
09/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,724	NGU, VICTOR ANOMAH	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-11,13-20 and 30-36* is/are pending in the application.

4a) Of the above claim(s) *35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11,13-20 and 30-34* is/are rejected.

7)☒ Claim(s) *13 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 6/19/2008. The status of the claims is as follows: claims 7-11, 13-20 and 30-34 are under current examination and claims 35-36 are drawn to non-elected inventions.

Please note that this case has been transferred to another Examiner and all future correspondences regarding this application should be directed to Michelle Horning of AU 1648.

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 6/19/2008 is acknowledged.

Information Disclosure Statement

No IDS has been submitted for consideration.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title "Vaccine and Method of Use" is nebulous.

Claim Objections

Claim 13 is objected to because of the following informalities: for the use of random periods throughout the claim; see lines 4 and 6. Appropriate correction is required.

Claim 16 is objected to because of the following informalities: for the use of a random hyphen (see line 2) and excessive commas in ",the," (see line 3). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim reads "culturing an infectious from said biological fluid" and it is not clear what is infectious.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11, 13-20 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a making a composition in which antigen are isolated, does not reasonably provide enablement for a "therapeutic vaccine". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors.

Nature of the invention. The claims are drawn to a method of making a therapeutic vaccine.

Scope of the invention. All claims are broad with respect to what the therapeutic vaccine is for. The claims are drawn to a lipid-containing infectious organism and in view of the instant disclosure, no definition is provided with respect to a "lipid-containing infectious organism". Note that "microorganism" is defined as bacteria, fungi and parasites but viruses are excluded (see paragraph 6, Background of the Invention). Paragraph 25 describes the viral envelope like a cell membrane as containing phospho-lipoproteins.

State of the prior art. The prior art describes the claimed methods with respect to making the composition (see Ngu 2001).

Working examples. The examples describe a method in which HIV antigens were isolated from HIV patients, using the claimed method. Following administration of the composition, the viral load and CD4 were counted (see page 26).

Guidance in the specification. The specification provides the requirements of an effective preventative vaccine on page 27. The specification provides the following recitation: "the HIV vaccine should provoke an immune response that kills the virus in the infected person". According to the specification, the essential feature of the invention is that a part of a person's immune system contained in his peripheral leukocytes can be vaccinated *in vitro* in a medium free of HIV and lipid-containing infectious agent before being re-injected into the person (see page 28). While only hypothetical, this feature has yet to be proven to be essential to a therapeutic vaccine by the Applicant or by the prior art.

Predictability of the art. There is no way one could predict whether a composition resulting from the claimed method would lead to a successful therapeutic vaccine.

Amount of experimentation necessary. Much undue experimentation would be necessary in order to achieve a therapeutic vaccine against lipid-containing organisms as so broadly claimed, such as actual data supporting the composition as a successful vaccine.

Given the discussion above, it would require undue experimentation for the ordinary artisan to perform the full scope of the method as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ngu (2001).

Ngu describes both an effective vaccine and immunotherapy against HIV. Page 5 provides that blood was taken from patients concerned (HIV infected) and either ether or chloroform was used in order to destroy the viral envelope. The solvent is removed and the residue constitutes the vaccine comprising only the HIV antigens (column 1, page 5). Using this composition, the author then treated leukocytes *in vitro* isolated from the person concerned and the treated cells were re-injected back into the patient.

Purification of the leukocytes is described on pages 5 and 7 and the author claims that all traces of the serum were removed. Thus, the above claims are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-11, 17-20 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ngu as further evidenced by Franks (1998).

The teachings of Ngu are applied as they are above. Ngu does not provide additional steps to concentrate or dilute a sample or specific ratios of chloroform to biological fluid. Additionally, Ngu does not express a procedure in which extraction includes mixing, swirling, vortexing and rotating. Lastly, Ngu does not describe extracting and treating a biological fluid from one infected person and treating the leukocytes isolated from a second person in which both persons are infected with the same lipid-containing infectious organism.

Note that concentrating or diluting samples are obvious steps for the ordinary artisan to do in order to gain optimization, including altering the antigen concentrations for inducing optimal effects. Further, the process of lyophilization in order to concentrate a sample is well taught in the prior art (see whole document by Franks). Altering the ratios of the chloroform to biological fluids is also considered an optimization through

routine experimentation (see MPEP 2144.05). With respect to mixing, swirling, vortexing and rotating, this is also obvious to the ordinary artisan to do in order to gain homogeneity, particularly when two different samples are combined. In this case, claim 30 is drawn to these procedures in the step of extracting which involves combining a lipid-extracting solvent with a biological fluid. Lastly, the teachings of Ngu does not describe extracting and further treating a biological fluid from one infected person and treating the leukocytes with the first sample isolated from a second person in which both persons are infected with the same lipid-containing infectious organism. Note that such a method is obvious to the ordinary artisan given both persons are infected by the *same exact lipid-containing infectious organism*. As described by Ngu, it is the HIV antigens that are isolated from its viral membrane that is used to treat the leukocyte fraction and such antigens would be the same if the infectious organism is identical, regardless of its source. It would have been obvious to perform any method step in order to achieve optimal results or to use lipid-containing infectious organism vaccines (e.g. HIV antigens) regardless of its source for the treatment of the same exact lipid-containing infectious organism (e.g. HIV). There would have been a reasonable expectation of success (in including altering solution ratios, mixing two different samples or using a drug specific for a disease in treating that specific disease) because this is widely practiced in the prior art. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648